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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,404	04/20/2004	Colin Henry Self	44008-010200	5958

32361 7590 11/30/2006

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EXAMINER	
TUNGATURTHI, PARITHOSH K	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/829,404	SELF, COLIN HENRY	
	Examiner	Art Unit	
	David Humphrey	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments and Amendments

1. Claims 17-24 are pending.

Claims 17-24 are amended.

Claims 17-24 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections

Oath/Declaration

3. The objection to the oath for citing the incorrect application number for foreign priority under 35 U.S.C. 119 is withdrawn due to Applicant's submission of a new Oath.

Specification

4. The objection to the specification for not containing the updated status (pending, allowed, etc.) of all parent priority applications in the first line of the specification is withdrawn due to Applicant's amendment to the specification.

Claim objections

5. The objection to claims 17-24 because the text of any claims added by amendment must not be underlined is withdrawn due to Applicant's amendments to the claims.

Claim Rejections - 35 USC § 112, second paragraph

6. a. The rejection of claim 17 as vague and indefinite for the recitation, "an analyte which is a member of a binding pair" is withdrawn due to Applicant's arguments.

b. The rejection of claim 17 as vague and indefinite for the recitation, "assaying the macromolecule for the presence of the analyte" is withdrawn due to Applicant's arguments.

c. The rejection of claim 17 since the limitation "the capability" in line 4 and in line 7 lacks antecedent basis is withdrawn due to Applicant's amendment to the claim.

d. The rejection of claim 17 since the limitation "the inhibited antibody" in line 5 lacks antecedent basis is withdrawn due to Applicant's amendment to the claim.

e. The rejection of claim 18 as vague and indefinite for the recitation of "a first antibody component capable of binding a receptor" is withdrawn due to Applicant's amendment to the claim.

f. The rejection of claim 19 since the limitation "the active site" in line 2 lacks antecedent basis is withdrawn due to Applicant's amendment to the claim.

g. The rejection of claim 20 as vague and indefinite for the recitation of "the second antibody component is *against* an enzyme" is withdrawn due to Applicant's amendment to the claim.

h. The rejection of claims 23 and 24 since the limitation "the electromagnetic radiation" lacks antecedent basis is withdrawn due to Applicant's amendments to the claims.

New Grounds of Objection

Claim Objections

7. Claim 19 is objected to because of the following informalities: a typographical error. In line 3, the word "free" is missing an "r". Appropriate correction is required.

Maintained Rejections and News Grounds of Rejection

Claim Rejections - 35 USC § 112, second paragraph

8. a. The rejection of Claim 17 as vague and indefinite for the recitation of analyzing a mixture is maintained. Applicant's amendment to the claim does not clarify what components are in the mixture. Since the specification does not define a "mixture", the mixture could include anything. Accordingly, one of ordinary skill in the art would be unable to determine the metes and bounds of the claimed invention.

b. The rejection of claim 19 as vague and indefinite for the recitation, "parts of antibodies which retain the active site" is maintained. Applicant's amendment to the claim does not resolve the indefinite nature of the "active site" of antibodies. It is still

unclear why the term "active site" which is commonly used to refer to the binding site of substrates for enzymes is used in this instant case, unless the antibodies are catalytic. Therefore, the metes and bounds of the claim cannot be determined.

c. Claim 19 recites the limitation "the Fc regions" in line 3. There is insufficient antecedent basis for this limitation in the claim.

d. Claim 19 is vague and indefinite for the recitation of Fab or Fab_2' [sic] fragments since Fabs are not bispecific, see claim 18 upon which claim 19 depends.

e. Claim 19 is vague and indefinite for the recitation of Fab_2' fragments. It is unclear what constitutes an Fab_2' fragment. One possibility is that the antbody fragment is $F(ab')_2$.

Claim Rejections - 35 USC § 112, first paragraph

9. The rejection of claims 17-24 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained.

Applicant argues that the claims cover a well-defined, fully enabled assay. Applicant cites paragraphs [0072 through 0077] of the published specification corresponding to pages 15-16 of the specification as filed which enables the claimed method. Applicant further argues that the antibody will only react with the analyte of interest and not just any analyte as the Examiner contends. Similarly, the macromolecule will interact with only macromolecule containing the photocleavable

moiety and not just any macromolecules, see Remarks, page 6, last paragraph, through page 7, first full paragraph.

Applicant's arguments have been carefully considered but found not persuasive. The portion of the specification cited by Applicant's provides an example of an assay involving a bispecific antibody. However, the example is very general and provides no specific guidance as to how one of ordinary skill in the art could implement the claimed assay. As previously made of record, the claims are very broad and encompass methods of using unspecified mixtures, macromolecules, and antibodies to determine the presence of any analytes.

Applicant did not respond to the issues set forth by the Examiner in the previous Office action. Applicant's claims and specification do no clearly or specifically recite the claimed invention. For example, Example 1, on page 21, discloses only how to make an antibody that binds to CEA and reversibly binds to alkaline phosphatase. Example 2 does not identify what antibody is used, whether or not alkaline phosphatase is added, and what analyte is analyzed on the human carcinoma cell line. On page 23, Examples 3-5 present various methods for producing antibodies or antibody fragments that have been established by others. Examples 1A, 2A, 3B, and 5A, comprise irradiating the bispecific antibodies before adding them to the cells. These examples are not commensurate in scope with the claims which recite mixing the inhibited antibody with a mixture prior to exposing the mixture to electromagnetic energy. Example 3A discloses a method wherein the mixture is irradiated after the antibodies have been added. However, irradiation time vs. visual color does not provide evidence that more enzyme

is being activated. Although, Applicants have described that there are roughly 8-12 NPE residues per antibody molecule (see page 24, lines 8-10) that does preclude that some antibodies do not contain any NPE. This is evidenced by the initial color seen without any irradiation for the 5.0 micrograms/ml measurement. If enzyme activity already exists in the sample, it is unclear to what extent the activated antibody-enzyme conjugate contributes to the overall assay. In addition, if this example was truly demonstrated activation of an antibody-enzyme complex, the rate of reaction for the 5.0 micrograms/ml reaction should be 2x that of the 2.5 micrograms/ml sample, which it is clearly not. In fact, one could argue that the rate of reaction for the 2.5 micrograms/ml sample is faster. The specification does not provide guidance commensurate in scope with the claims.

The disclosure does not demonstrate sufficient evidence to support Applicants' claim to a method of analyzing a mixture using an antibody capable of binding an analyte and a macromolecule which the capability of binding to the macromolecule is reversibly inhibited, exposing the mixture to electromagnetic energy to allow the macromolecule to bind, and assaying the macromolecule for the presence of the analyte. All of the factors considered in the sections above, underscores the criticality of providing working examples in the specification for an unpredictable art such as providing gene therapy to animals to treating cardiovascular diseases.

Therefore, one of ordinary skill in the art would conclude that a method of analyzing a mixture to determine the presence of an analyte would require undue experimentation in order to use the invention as claimed by the Applicant.

Conclusion

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Humphrey whose telephone number is (571) 272-5544. The examiner can normally be reached on Mon-Fri 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Humphrey, Ph.D.

November 22, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER